

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 3, 2020

Katherine Poiesz Regulatory Manager The Procter & Gamble Company 5299 Spring Grove Avenue Cincinnati, OH 45217

Subject: Label Amendment: Emerging Viral Pathogens Claim

Product Name: "Comet Disinfecting Bathroom Cleaner"

EPA Registration Number: 3573-54 Application Date: March 10, 2020

Decision Number: 561084

Dear Ms. Poiesz:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging\_viral\_pathogen\_program\_guidance\_final\_8\_19\_16\_001\_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

- 2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
- 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
    - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
      - A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
      - B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
      - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
    - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page

(www.oie.int/wahis 2/public/wahid.php/Diseaseinformation/WI).

- A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is large, non-enveloped virus and enveloped virus.
- B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
- 4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

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5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Norovirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,

Steven Snyderman, Acting Product Manager 33

Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Steven Inyderman

Enclosure: stamped label

# FRONT LABEL

COMET DISINFECTING BATHROOM CLEANER \ alternate brand name \ product name

ACTIVE INGREDIENT: Citric acid .......6.0% INERT \ OTHER INGREDIENTS: \*94.0% 

\*Cleaning Agents, Quality Control Agents, Perfume and Water.

ACCEPTED

04/03/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 3573-54

KEEP OUT OF REACH OF CHILDREN

CAUTION: MAY BE HARMFUL IF SWALLOWED. See back \ side panel for other precautions.

Net Weight Statement

# [Optional]:

Ready-to-Use

Refill

Disinfectant

Hospital Use \ Medical Environment Disinfectant

For Automatic Dilution

[Closed Loop] Dilution Control

Dilution Control [Closed Loop]

[Dilute2Go] [ProFill] [EZFill] [Portable] [Mobile] [Dispensing] [Dilution] [Device] [Unit] [System]

Concentrate

5X Concentrate

# [41] [3-20] [X] [X-X] [XX] [X-XX] [XX-XX] [other unique product code] [0]

{Note to reviewer: X may represent a single number or multiple numbers unique to this product}

[Unique] [Product] [Identification] [ID] [Order] [Catalog] [Reorder] [Code] [Number] [No.] [:] [3-20] [X] [X-X] [XX] [X-XX] [XX-XX] [other unique product code]

Bactericide\Bactericidal Virucide†\Virucidal† Sanitizer Institutional Commercial [For] Commercial Use

P&G ProLine \ Procter & Gamble Professional \ P&G Professional [or logo]

For Institutional Use \ For Industrial and Institutional Use NOT FOR RETAIL SALE

# BACK\SIDE LABEL

COMET DISINFECTING BATHROOM CLEANER \ alternate brand name \ product name

Note to reviewer: The Directions for Use on the final product label will display one of the two sets of general cleaning directions listed below. The Direction for Use with either display the bullet points of general cleaning directions (up to and including the "For best results \ On tougher soils..." paragraph) OR the alternate general cleaning directions beginning with the "GENERAL CLEANING [DIRECTIONS]...." paragraph up to and including the "Rinse all [kitchen] surfaces...." paragraph. The final product label will then display the "TO [CLEAN AND] DISINFECT (hard, non-porous surfaces)..." directions on the ready-to-use containers, or the "TO [CLEAN AND] SANITIZE (hard, non-porous surfaces)..." directions on any container to complete the Directions for Use.

**DIRECTIONS FOR [HOUSEHOLD] [INSTITUTIONAL] [COMMERCIAL] USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

- Lift flap and lock into arrow on top of sprayer. Picture of sprayer top. [or for gallon size refill container only: Refill [into] properly labeled spray bottle[s]. \Refill [only] [properly labeled] [product name] spray bottle[s]. Picture of refill process.]
- Spray soiled surface until thoroughly covered [Picture of spraying action]
- Wipe with a damp cloth [or sponge]... for a shiny clean surface [or Spray soiled surfaces until thoroughly covered and wipe with a damp cloth [or sponge] [Picture of wiping action on bathroom surface]

For best results \ On tougher soils, allow product to remain on surface longer [*or* allow to soak]. [For daily cleaning, dilute 1 part product to [plus] 3 \ 4 parts water [([1] 8 oz [cup] per 32 oz spray bottle \ 6.4 oz per 32 oz spray bottle)]. Spray and wipe. On tougher soils, use product full strength.]

OR, in place of the above usage instructions, use the following general cleaning directions up to and including the "Rinse all [kitchen]..." paragraph:

**DIRECTIONS FOR [HOUSEHOLD] [INSTITUTIONAL] [COMMERCIAL] USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**GENERAL CLEANING [DIRECTIONS]:** Apply to hard, non-porous surfaces. Spray \ Pour directly onto surface [or damp sponge] [or cloth] [or paper towel] [or towel]. Rinse or wipe clean. For [On] tough stains [or soil], let soak \ stand. \ For tougher soils, allow to soak. [(For non-disinfecting light \ daily [duty] [soil] cleaning, dilute up to 1 part concentrate \ product to 9 \ 19 parts water).]

Rinse all [kitchen] surfaces that come in contact with food [such as countertops] with potable water before reuse. [Do not use on utensils, glasses or dishes.]

**TO [CLEAN AND] DISINFECT (hard, non-porous surfaces):** Clean surfaces prior to disinfecting heavily soiled areas. \For highly \heavily soiled areas, clean before disinfecting \following disinfecting directions. Thoroughly wet hard, non-porous surfaces [with [disinfecting] solution] for 10 minutes, then rinse or wipe clean. \Spray product on surface and let stand for 10 minutes [before wiping]. [TOILET BOWLS [AND URINALS]: Empty water from the toilet bowl [or urinal]. [Hold 6-8" from surface.] Spray [covering] exposed surfaces. Brush thoroughly [over surfaces including the rim to completely wet surfaces], let stand for 10 minutes, then flush.]

TO [CLEAN AND] SANITIZE (hard, non-porous surfaces): Clean surfaces prior to sanitizing heavily soiled areas. \ For heavily soiled areas, clean before sanitizing \ following sanitizing directions. Thoroughly wet hard, non-porous surfaces [with [sanitizing] solution] for 5 minutes, then rinse or wipe clean. \ Spray product on surface and let stand 5 minutes [before wiping]. [TOILET BOWLS [AND URINALS]: Empty water from the toilet bowl [or urinal]. [Hold 6-8" from surface.] Spray [covering] exposed surfaces. Brush thoroughly [over surfaces including the rim to completely wet surfaces], let stand for 5 minutes, then flush.] [For light \ daily [duty] [soil] cleaning & sanitizing, dilute \ mix 1 part concentrate \ product to \ with 4 parts water.]

To Prepare [Disinfecting or Sanitizing] Solution using Dilution Center

**Automatic Dilution Container Instructions** 

ATTACHING THIS PRODUCT TO THE [P&G] [AUTOMATIC] DILUTION CENTER: Remove the [white] shipping cap. [Picture of automatic dilution center process] Screw on [light] [green] dispensing cap from dilution center [product tube]. Push down while twisting.

[PREPARING SANITIZING SOLUTION: Dilute \ Mix 1 part [of this] product \ concentrate with 4 parts water using the [P&G] [AUTOMATIC] dilution center.]

[PREPARING DISINFECTING SOLUTION [(UNDILUTED)]: Set dilution center to by-pass; if dilution center does not dispense undiluted product, remove bottle from dilution center and remove bottle plug.]

Note to Reviewer: The order of the Directions for Use might differ on the product label from what is listed above, but the content of the information will be the same.

KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED ENVIRONMENTAL SURFACES\OBJECTS PREVIOUSLY SOILED WITH BLOOD\BODY FLUIDS, in health care settings in which there is an expected likelihood of soiling of inanimate surfaces\objects with blood or body fluids, and in which the surfaces\objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1(HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES\OBJECTS SOILED WITH BLOOD\BODY FLUIDS.

**PERSONAL PROTECTION:** When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye protection.

CLEANING PROCEDURE: Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of this product.

**CONTACT TIME:** Thoroughly wet surfaces with disinfecting solution for 10 minutes, then rinse or wipe clean. Please consult the usage directions to determine the appropriate contact times for other organisms.

**DISPOSAL OF INFECTIOUS MATERIAL:** Blood, body fluids, cleaning materials and clothing must be autoclaved and disposed of according to local regulations for infectious waste disposal.

Note to Reviewer: The first aid information provided below is compliant with PR 2001-1 and was submitted to the Agency for review on June 25, 2003. The "Do not mix" statement has been changed to provide more clarity.

# PRECAUTIONARY STATEMENT: HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION:** Causes eye irritation. Avoid contact with eyes. May be harmful if swallowed. Do not mix with other cleaning products or chemicals as irritating fumes may be formed.

**FIRST AID: IF IN EYES**, hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF SWALLOWED,** drink 1-2 glasses of water and call a doctor or poison control center (product contains an alcohol ethoxylate). Do not induce vomiting unless told to do so by a poison control center or doctor.

Have the product container or label with you when calling or going for treatment.

Note to Reviewer: The boxed format as listed above will be used if label space permits; otherwise, an alternative format will be used to emphasize the text, such as bullet points, increased white space, increased font size or different colors.

# {ALTERNATE LANGUAGE FOR PORTABLE DILUTION / DISPENSING SYSTEMS}

{Note to Reviewer: Product containers equipped with these portable dilution /dispensing system will clearly indicate on the labels, that the diluted product solution dispensed from these containers is for cleaning and sanitizing of hard, non-porous surfaces, only. Additionally, the optional text below will only appear on containers equipped with portable dilution / dispensing systems}

## <<System Descriptors:>>

[The] ProFill [Dispensing] [Unit] [System]

[The] EZFill [Dispensing] [Unit] [System]

[The] Dilute2Go [Dispensing] [Unit] [System] [D2G]

[The] [MDU] [MDD] [Mobile] [Dispensing] [Dilution] [Device] [Unit] [System]

[The] [PDU] [PDD] [Portable] [Dispensing] [Dilution] [Device] [Unit] [System]

## <<Optional Text:>>

[Simple.] [Smart.] [Clever.] [Designed to Dilute.] [Ready-to-Dilute.] [Accurate.] [Reduce product overuse [waste].] [Effective.] [No chemical contact [with concentrate].] [No risk of [product] cross contamination.] [Easy operation.] [Minimal training.] [Durable [during] [use] [transport].] [Effective.] [Sealed bottle.] [Dilution control.] [Portable [concentrate] [dilution].] [Plug and Go.] [Connect and Go.]

[{insert appropriate number}] [gpm] [gallons per minute] [flow] [fill] [rate][.]

[Dilution ratio based on product used.]

[!][TURN OFF water supply after use and disconnect][.][!]

# <<Optional Text:>>

[[The] [diluted] [product] [solution] dispensed from this container can be used to [clean and] sanitize hard, non-porous surfaces][.]

[This [1.5L] bottle makes 7.5L of diluted [sanitizing] product.]

[This [4.5L] bottle makes 22.5L of diluted [sanitizing] product.]

#### TO FILL SPRAYER[S] [BUCKET[S]][:]

- 1. Attach [<<system descriptor>>] [unit] to water source [using [water] [hose] [and] [or] [quick-connect] [provided]]. [Turn on water supply [to pressurize unit].]
- 2. Pull back [small] [green] [{other color}] locking tab from {[off] [<< representative "off" icon>>]} notch [with thumb].
- 3. While holding back tab, use opposite hand to slide [yellow] [{other color}] selector bar to {[spray bottle] [bucket] [<<representative "spray bottle" icon>>] [<<representative "bucket" icon>>]} [position] to dispense product. [The {[faucet] [<<representative "faucet" icon>>]} [position] dispenses water only [for rinsing]].
- 4. {Note to reviewer: One or both of the following statements may be used} [For spray bottle[s] [applications]:] Insert spray bottle under [dispenser] nozzle. <<and/or>>
  - [For bucket[s] [applications]:] {[Hold] [Hang]} [dispenser] nozzle [over bucket] [on bucket rim].
- 5. Push down [red] [{other color}] trigger [to fill spray bottle] [to fill bucket] [for product flow] [into a bottle] [into other container]. [Release [red] [{other color}] [trigger] to stop.]
- 6. [See [online] [service] [device] [instruction] [manual] [insert] for [more] [detailed] [usage] information.)

## TO TRANSPORT[:]

- 1. [Pull back [small] [green] [{other color}] locking tab and] slide [yellow] [{other color}] selector bar to {[faucet] [<<representative "faucet" icon>>]} [position]. [Unit now dispenses water only [and can be used for rinsing] [by pushing down [red] [{other color}] trigger].]
- 2. Turn off water [at [the] source].
- 3. [While still in the {[faucet] [<< representative "faucet" icon>>]} [position],] push down [red] [{other color}] trigger to release water pressure. [A small amount of water will be discharged.] [Pressure will be released from the unit.]
- 4. [Once pressure is released [from the unit],] [pull back [small] [green] [{other color}] locking tab and] slide [yellow] [{other color}] selector bar to {[off] [<<representative "off" icon>>]} [position]. [Disconnect water hose from unit.] [[Unit] [<<System Descriptor>>] is now ready for transport.]

# <<REPRESENTATIVE ICONS INDICATED IN INSTRUCTIONS >>

{Note to reviewer: the following representative icons may be used to demonstrate directions for use.}



STORAGE/DISPOSAL: Store in a cool place.

# (READY-TO-USE APPLICATION:)

Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. \((or)\)

(Nonrefillable container.) Do not reuse or refill this container (except as described in the directions for use). Wrap [container] and put in trash or offer for recycling if available. \(\lambda or \rightarrow \rightarrow

(Nonrefillable container.) Do not reuse or refill this container (except as described in the directions for use). Wrap [container] and put in trash or offer for reconditioning if appropriate. \ (or)

Always refill/reuse this container as described in the directions for use. Otherwise, wrap [container] and put in trash or offer for recycling if available. \(\lambda or \)

Only refill/reuse this container as described in the directions for use. Otherwise, wrap [container] and put in trash or offer for recycling if available. \ (or)

Refill/reuse this container only as described in directions for use. Otherwise, wrap [container] and put in trash or offer for recycling if available.

# (DILUTABLE APPLICATION – FIVE GALLONS OR LESS:)

Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. \ (or)

(Nonrefillable container.) Do not reuse or refill this container (except as described in the directions for use). Wrap [container] and put in trash or offer for recycling if available. \(\lambda or \rightarrow \rightarrow

(Nonrefillable container.) Do not reuse or refill this container (except as described in the directions for use). Wrap [container] and put in trash or offer for reconditioning if appropriate. \ (or)

Always refill/reuse this container as described in the directions for use. Otherwise, wrap [container] and put in trash or offer for recycling if available. \(\lambda or \)

Only refill/reuse this container as described in the directions for use. Otherwise, wrap [container] and put in trash or offer for recycling if available. \(\lambda or \)

Refill/reuse this container only as described in directions for use. Otherwise, wrap [container] and put in trash or offer for recycling if available.

Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

#### [Refill:]

- Refill only with [product name]
- Refill [1 QT] [/] [32 oz] sprayer size from [this convenient] container.
- Use only in [product name] spray bottle.
- Only refill [convenient] sprayer with [product name] [this product].
- [Only] refill sprayer with [x oz.][only].
- [Do not dilute].

Recycling logo Bottle made from 35% post-consumer recycled plastic.

[Contains] no phosphorus \ phosphate.

Will not harm septic tanks.

UPC code

Kosher Symbol

ТМ

®

0

Phone symbol Questions? [Comments?] [[M]SDS?] [A [Material] Safety Data Sheet ([M]SDS) is available upon request from your supplier.]

[Call Toll-Free] X-XXX-XXX-XXXX

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pgbrands.com [or www.pgproline.com] [or pgpro.com] [or appropriate phone number and website] {Note to Reviewer: The website URL may also be provided as a Quick Response (QR) code} [QR Code icon]

[Use your [smart]phone] [to] [and] [scan] [the] [this] [tag] [code] [to] [learn] [see] [more] [uses] [information] [videos] [on how to use] [on] [for] [this product] [for] [how to] [tips] [DATA RATES [MAY] APPLY]

[MADE IN USA.] Distributed by PROCTER & GAMBLE[,] [1 P&G Plaza][,] Cincinnati, OH 45202-3315. EPA Reg. No. 3573-54

EPA Est. No. 3573-MO-1 [or 52379-MI-002] [or a blank box in which the appropriate establishment number is inkjetted at the manufacturing site. This option allows the flexibility to use one supply of product labels for product manufactured at multiple sites. The establishment number ink-jetted into this box would be 3573-MO-1 or 52379-MI-002 depending on where the product is manufactured.]

Patent statement

Comet and associated trademarks and design elements are owned and licensed by Prestige Brands. © [year] Prestige Brands. All rights reserved.

# Claims for Containers with Disinfecting Instructions (front, back or side label):

#### DISINFECTION

This product [is a] hospital use \ medical environment disinfectant [that] kills \ cleans and kills \ eliminates \ destroys \ removes [a] broad \ wide range \ spectrum of bacteria [and] viruses† \ germs\* (*list at least one bacterium and one virus from lists below*) \ and prevents the spread of *list of bacteria and/or options:* 

- Salmonella enterica (Salmonella) \ Salmonella enterica (ATCC 10708)
- Staphylococcus aureus (Staph) \ Staphylococcus aureus (ATCC 6538)
- Pseudomonas aeruginosa (Pseudomonas) \ Pseudomonas aeruginosa (ATCC 15422)
- Proteus mirabilis (Proteus) \ Proteus mirabilis (ATCC 9240)
- Escherichia coli \ E. coli \ Escherichia coli (ATCC 11229)
- Escherichia coli O157:H7 \ E. coli O157:H7\ Pathogenic E coli \ E. coli O157:H7 (ATCC 35150)
- Shigella dysenteriae \ Shigella dysenteriae (ATCC 11835)
- Staphylococcus aureus CA MRSA \ Community Associated Methicillin Resistant Staphylococcus aureus- CA MRSA, PVL Positive \ Community Associated Methicillin Resistant Staphylococcus aureus \ Community Associated MRSA \ Community Associated Methicillin Resistant Staphylococcus aureus- CA MRSA, PVL Positive (NARSA # NRS 192)
- Vancomycin Resistant Enterococcus faecalis VRE\ Enterococcus faecalis (Vancomycin Resistant) \ Enterococcus faecalis (VRE/VR) \ Vancomycin Resistant Enterococcus faecalis – VRE (ATCC 51575)
- [Multi-drug Resistant‡] Acinetobacter baumannii \ Acinetobacter baumannii (ATCC 19606)

‡Ampicillin, Ampicillin/Sulbactam, Aztreonam, Ceftazidime, Cefotaxime, Cefazolin, Piperacillin, Piperacillin/Tazobactam, Trimethoprim/Sulfamethoxazole and Ticarcillin/Clavulanic acid

- Streptococcus pyogenes (Flesh Eating Strain BIRD M3)
- Campylobacter jejuni (Campylobacter) \ Campylobacter jejuni (ATCC 29428)
- Klebsiella pneumoniae (Klebsiella) \ Klebsiella pneumoniae (ATCC 4352)
- Enterobacter aerogenes (Enterobacter) \ Enterobacter aerogenes (ATCC 13048)
- Klebsiella pneumoniae NDM-1 positive \ Klebsiella pneumoniae NDM-1 positive (CDC 1000527) \ K. pneumoniae NDM-1 positive \ NDM-1 positive Klebsiella pneumoniae \ NDM-1 positive K. pneumoniae \ NDM-1 producing Klebsiella pneumoniae \ NDM-1 producing K. pneumoniae \ Carbapenem resistant Klebsiella pneumoniae \ Carbapenem resistant K. pneumoniae \ CR Klebsiella pneumoniae \ CR K. pneumoniae \ CRKP \ Carbapenemase-producing Klebsiella pneumoniae \ Carbapenemase-producing K. pneumoniae \ New Delhi Metallo beta lactamase (NDM) 1 producing K. pneumoniae \ New Delhi Metallo beta lactamase (NDM) 1 producing K. pneumoniae \ New Delhi Metallo beta lactamase-1 (NDM-1) producing Klebsiella pneumoniae \ Klebsiella pneumoniae Carbapenemase \ K. pneumoniae Carbapenemase \ K.
- Enterobacter cloacae NDM-1 positive \ Enterobacter cloacae NDM-1 positive (CDC 1000654) \ E. cloacae NDM-1 positive \ [NDM-1 positive Enterobacter cloacae \ NDM-1 positive E. cloacae \ NDM-1 producing Enterobacter cloacae \ NDM-1 producing E. cloacae \ Carbapenem resistant Enterobacter cloacae \ Carbapenem resistant E. cloacae \ CR Enterobacter cloacae \ CR E. cloacae \ Carbapenemase-producing Enterobacter cloacae \ Carbapenemase-producing E. cloacae \ New Delhi Metallo beta lactamase (NDM) 1 producing Enterobacter cloacae \ New Delhi Metallo beta lactamase (NDM) 1 producing E. cloacae \ New Delhi Metallo beta lactamase-1 (NDM-1) producing Enterobacter cloacae \ Enterobacter

- Clean and disinfects
- Disinfects as it cleans
- One step cleaner and disinfectant
- Disinfects [and deodorizes]
- Restroom \ Bathroom disinfectant
- Combines cleaning, disinfecting
- Disinfecting cleaner
- Disinfectant
- Hospital Use \ Medical
   Environment Disinfectant For use on commercial product only
- Bactericide \ Bactericidal
- Virucide†\Virucidal†
- Disinfects and deodorizes by killing bacteria [and controlling odors]
- Cleans [and] [shines] [and]
   disinfects [and] [deodorizes]
   [washable] [restroom \ bathroom]
   [surfaces] [and] [fixtures]
- One step cleaner & disinfectant
- Respiratory illnesses attributable to Pandemic 2009 H1N1are caused by influenza A virus. This product (Product Name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.

- *cloacae* Carbapenemase \ *E.cloacae* Carbapenemase \ *ECe*C
- Escherichia coli NDM-1 positive \ Escherichia coli NDM-1 positive (CDC 1001728) \ E. coli NDM-1 positive \ NDM-1 positive Escherichia coli \ NDM-1 positive E. coli \ NDM-1 producing Escherichia coli \ NDM-1 producing E. coli \ Carbapenem resistant Escherichia coli \ Carbapenem resistant E. coli \ CR Escherichia coli \ CR E. coli \ CRECi \ Carbapenemase-producing Escherichia coli \ Carbapenemase-producing E. coli \ New Delhi Metallo beta lactamase (NDM) 1 producing Escherichia coli \ New Delhi Metallo beta lactamase (NDM) 1 producing E. coli \ New Delhi Metallo beta lactamase \ (NDM-1) producing Escherichia coli \ Escherichia coli \ Carbapenemase \ E. coli \
- Klebsiella oxytoca \ Klebsiella oxytoca (ATCC 13182)
- Enterococcus faecium \ Enterococcus faecium (ATCC 51559)
- Burkholderia cepacia \ Burkholderia cepacia (ATCC 25416)
- Staphylococcus saprophyticus \ Staphylococcus saprophyticus (ATCC 15305)
- *Yersinia enterocolitica \ Yersinia enterocolitica (ATCC 23715)*
- Streptococcus pneumoniae \ Streptococcus pneumoniae (ATCC 6305)
- Staphylococcus hominis \ Staphylococcus hominis (ATCC 25615)
- Enterobacter cloacae \ Enterobacter cloacae (ATCC 13047)
- Corynebacterium ammoniagenes \ Corynebacterium ammoniagenes (ATCC 6872)
- Enterococcus faecalis \ Enterococcus faecalis (ATCC 29212)
- Shigella flexneri \ Shigella flexneri (ATCC 9380)
- Shigella sonnei \ Shigella sonnei (ATCC 25931)
- Staphylococcus haemolyticus \ Staphylococcus haemolyticus (ATCC 29969)

# and list of viruses and/or options (†list at least one of the viruses below):

- Avian Influenza A [virus] \ Avian Influenza A (H3N2) [virus]
- Duck Hepatitis B virus
- Human Hepatitis B virus (Duck Hepatitis B virus surrogate) \ Human Hepatitis B virus (Duck Hepatitis B virus) \ Hepatitis B virus (Duck Hepatitis B virus) \ Human Hepatitis B virus \ Hepatitis B virus \ Virus
- Feline calicivirus
- Norovirus \ Norovirus (Feline calicivirus as surrogate)
- Bovine Viral Diarrhea virus
- Human Hepatitis C virus (Bovine Viral Diarrhea virus surrogate) \ Human Hepatitis C Virus (Bovine Viral Diarrhea virus) \ Hepatitis C Virus (Bovine Viral Diarrhea virus) \ Human Hepatitis C virus \ Hepatitis C virus
- Rotavirus
- Human Immunodeficiency Virus type I \ HIV-1
- 2009-H1N1 Influenza A virus (Novel H1N1) \ 2009-H1N1 Influenza A virus

## Additional claims (front, back or side label):

#### **SANITIZING**

- Kills \ Eliminates \ Destroys \ Removes [and prevents cross contamination of] 99.9% of Staphylococcus aureus (Staph) and Enterobacter aerogenes (Enterobac) (For products that require dilution only:) when 1 part product \ concentrate to 4 parts water (171 ppm hard water \ 10 gpg water hardness) [and 5% fetal bovine serum].
- Kills \ Eliminates \ Destroys \ Removes [and prevents cross contamination of] 99.9% of bacteria (For products that require dilution only:) when diluted 1 part product \ concentrate to 4 parts water (171 ppm hard water \ 10 gpg water hardness) [and 5% fetal bovine serum].
- Cleans and kills \ eliminates \ destroys \ removes 99.9% of bacteria (For products that require dilution only:) when diluted 1 part product \ concentrate to 4 parts water (171 ppm hard water \ 10 gpg water hardness) [and 5% fetal bovine serum].

- Sanitizer
- Antibacterial Cleaner
- Cleaner / sanitizer
- Sanitizing cleaner
- Cleans and sanitizes
- Sanitizes non-food contact surfaces
- Leaves surfaces [clean and] sanitized

# CLEANING AND DEODORIZING CLAIMS

- Cuts through \ Eliminates \ Removes \ Cleans \
   Dissolves tough soap scum [and hard water stains] [from bathtubs] [and] [showers] [and] [shower stalls]
- Dissolves \ Cleans \ Cuts through tough [stains] [soap scum] [and] [hard water stains]
- Removes \ Eliminates \ Cleans tough [stains] [soap scum] [and] [hard water stains]
- Cleans [and] [shines] [and] [deodorizes]
   [washable] [restroom \ bathroom] [surfaces]
   [and] [fixtures]
- Cleans restroom \ bathroom surfaces, such as counters, sinks, tubs, toilet exteriors, showers, floors, etc.
- Cleans without scrubbing
- Restrooms great all-around restroom \ bathroom cleaner
- Makes employee tasks simple, cutting through soap scum [and] [hard water stains]
- Designed to help improve cleaning productivity
- Saves time little to no scrubbing needed!
- Minimizes training time

- Deodorizer
- Deodorizes
- Freshens
- Freshens \ Deodorizes as you clean
- Powerful restroom \ bathroom cleaner
- Penetrates [and dissolves] tough soap scum and hard water stains [without scrubbing]
- Penetrates tough restroom \ bathroom soils without scrubbing
- Non-abrasive
- Cleans most surfaces
- Designed to improve cleaning productivity
- No scrubbing
- Minimizes training time
- Fewer products no need for separate deodorizer
- Non-abrasive [formula] [won't scratch surfaces]
- Rinses away easily
- Eliminates \ Removes odors caused by bacteria
- Scum buster formula
- Heavy duty formula
- A clean you can trust
- Makes employee tasks \ job \ life simple \ easy
- Powers away soap scum and hard water stains in one step

## Additional claims (front, back or side label):

#### **NON-PESTICIDAL CLAIMS**

- Institutional [size] [use]
- Commercial
- Not harmful to \ will not harm septic tanks
- Suitable for septic tank systems [and] [wastewater systems] [and] [treatment plants]
- Developed \ Formulated \ Designed for [institutional] [restroom \ bathroom] use
- This product \ Product name complies with consumer volatile organic compound (VOC) \ VOC laws
- [Contains] no bleach
- {note to reviewer: the following text may be written in words or depicted via graphics}:

1 G [gal] [gallon] = 4 [-32 oz] [spray] bottles

Example graphic/icon:



- A clean you can trust
- Fresh \ pleasant scent

## For closed chemical container only:

- Tamper proof bottle
- Bottle \ Sealed bottle \ Container \ Closed chemical system designed for employee safety
- Bottle \ Sealed bottle \ Container \ Closed chemical system designed to prevent spills and accidental concentrate \ product exposure

For gallon size refill container and closed chemical container:

Concentrate

For gallon size refill container and closed chemical container that display dilution instructions to achieve sanitizing benefits:

• 5X Concentrate

# For spray container only:

For household use

## Additional claims (front, back or side label):

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This product may be used on [washable] hard non-porous [non-food contact] [exterior] surfaces in *(list of and/or options)* 

- Foodservice establishments
- Restaurants
- Bars
- Cafeterias
- [institutional] kitchen exteriors \ exterior surfaces
- fast food operations
- food storage areas
- medical environments
- hospitals
- nursing homes
- medical and dental offices and clinics
- operation rooms
- isolation wards
- medical research centers
- ambulance
- schools
- colleges
- dormitories
- classrooms
- athletic facilities
- gymnasiums
- locker rooms
- day care centers
- nurseries
- retail establishments
- supermarkets
- convenience stores
- dressing rooms
- laundries
- laundromats
- office buildings
- funeral homes

- laboratories
- recreational facilities
- health clubs
- household areas
- kitchen exteriors \ exterior surfaces
- bathrooms \ restrooms
- basements
- household garages
- automotive garages
- hoats
- ships
- campers
- RVs
- Trailers
- Mobile homes
- Cars
- Buses
- Trains
- Taxis
- Airplanes
- Transportation terminals
- Veterinary clinics
- Kennels
- Breeding and grooming establishments
- Pet \ animal quarters
- Zoos
- Pet shops
- Churches
- Manufacturing facilities
- Military installations
- Factories
- Motels
- hotels

#### TASK AREAS Task areas: Toilet exteriors Restroom \ bathroom surfaces Urinal exteriors Glazed Porcelain Countertops Fiberglass Sinks Glazed Ceramic **Fixtures** Stainless steel Showers/Tubs [Glazed] [Ceramic] Tile Shower walls and doors Sealed Synthetic \ Cultured Marble Laminated surfaces[s] Formica\*\* Plastic laminate Chrome Sealed granite Baked Enamel For all other surfaces, test on a small area before \*\*Formica is a registered trademark of the Formica Corporation. Do not use on NATURAL MARBLE.

#### Picture Icons

Picture Icons				
Restroom \ Bathroom	Kitchen surfaces	Kitchen appliance exteriors	Floor surfaces	
surfaces				
(bathtub, shower, sink,				
toilet exterior)				
Wall-Mounted				
Automatic Dilution				
System/Equipment				
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Additional Directions for Use. Note to reviewer, sanitizing directions may or may not be numbered.

To use Comet \ Comet Disinfecting-Sanitizing Bathroom Cleaner \ Alternate Brand Name \ Product Name as a disinfecting cleaner in the bathroom, use full strength and do not dilute.

To use Comet \ Comet Disinfecting-Sanitizing Bathroom Cleaner \ Alternate Brand Name \ Product Name as a sanitizing cleaner:

- 1. Fill 5-gallon dilution jug ½ full with water.
- 2. Add contents of 1 gallon \ Comet Disinfecting-Sanitizing Bathroom Cleaner \ Alternate Brand Name \ Product Name.
- 3. Top off jug with water
- 4. Gently shake to mix.
- 5. Dispense the solution directly into a spray bottle.

#### **EMERGING VIRAL PATHOGENS**

This product qualifies for emerging viral pathogen claims per the EPA's "Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-registered Disinfectant Labels" when used in accordance with the use directions indicated below.

{Note to Reviewer: These statements for claims against large non-enveloped and/or enveloped emerging pathogens shall not appear on marketed (final print) product labels.}

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped viruses
- Large Non-enveloped viruses

For an emerging viral pathogen that is a/an	follow the directions for use for the
	following organism(s) on the label
Enveloped virus	Norovirus
Large, non-enveloped virus	Norovirus

[Comet Disinfecting Bathroom Cleaner][This product] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [Comet Disinfecting Bathroom Cleaner][this product] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

#### AND/OR

[Name of illness/outbreak] is caused by [name of emerging virus]. [Comet Disinfecting Bathroom Cleaner][This product] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)]. Refer to the [CDC or OIE] website at [website address] for additional information.